DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94366d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 1000307162

October 16, 2003

Jacobus L. De Groot, Partner
John De Groot, Partner
31845 Road 92
Visalia, California 93291

WARNING LETTER

Dear Messrs. De Groot and De Groot:

An investigation of your dairy operation in Visalia, California conducted by our investigator on September 17 and 18, 2003, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4), and that you have caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351.

On or about June 18, 2003, you consigned a cow (identified by United States Department of Agriculture (USDA) laboratory report number 435776) to be slaughtered for human food at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 0.24 parts per million (ppm) penicillin in the kidney. This level exceeds the 0.05 ppm tolerance that has been established for residues of penicillin in cattle kidney (Title 21, Code of Federal Regulations, Section 556.510). The presence of penicillin at this level in edible tissues from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator observed the following:

1. Your firm fails to maintain an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling or in a written

prescription from your veterinarian, specifically, PEN-AQUEOUS (Penicillin G Procaine) and ToDay (Cephapirin Sodium).

2. Your firm fails to maintain a complete, written, medication treatment record system for your animals that includes all treatments, the amount of drug administered, the route of administration, and the person who administered the drug.

3. Your firm fails to maintain a drug inventory/accountability system.

Our investigator also observed that you are adulterating the drugs PEN-AQUEOUS (Penicillin G Procaine) and ToDay (Cephapirin Sodium) that your firm uses on cattle within the meaning of Section 501(a)(5) of the Act when you fail to use the drugs in conformance with their approved labeling.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action, such as seeking a seizure and/or injunction, without further notice.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the date you receive this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or that will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District